IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF IOWA CENTRAL DIVISION

KEMIN FOODS, L.C., and THE CATHOLIC UNIVERSITY OF AMERICA.

Plaintiffs,

VS.

PIGMENTOS VEGETALES DEL CENTRO S.A. DE C.V.,

Defendant.

No. 4:02-cv-40327

ORDER ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND PLAINTIFF'S MOTION TO STRIKE

Currently pending before the Court is Defendant's Motion for Summary Judgment (Clerk's No. 164) with its Amended Memorandum of Law in Support (Clerk's No. 175). Defendant moves the Court to grant summary judgment in its favor on all of the claims asserted in Plaintiff's Complaint and in Defendant's own Counterclaim. In conjunction with this motion is Plaintiff's motion to strike portions of Defendant's pleadings (Clerk's No. 176). Attorneys for Plaintiff are John F. Lynch, Susan K. Knoll, Scott W. Clark, and Ed Mansfield; attorneys for Defendant are G. Brian Pingel, Michael A. Dee, Camille L. Urban, and Adam Jones. Oral argument on these motions was held on August 19, 2004. The motions are now fully submitted and ready for ruling.

PROCEDURAL HISTORY

The Plaintiffs, Kemin Foods, L.C. ("Kemin") and The Catholic University of America, filed an infringement action against the Defendant, Pigmentos Vegetales del Centro S.A. de C.V. ("PIVEG"), on July 9, 2002. The lawsuit alleges infringement of two patents held by Kemin, U.S. Patent Nos. 5,382,714 ("the '714 patent") and 5,648,564 ("the '564 patent"), by PIVEG. In turn, PIVEG has alleged several counterclaims against Kemin relating to the patents-in-issue.

Trial is scheduled to begin September 13, 2004, and is scheduled to last for approximately ten days. On January 13, 2004, the Court issued an Order on Claim Construction (Clerk's No. 120), construing the relevant claims from both the '714 patent and the '564 patent.¹ The Court amended this order on May 18, 2004, when it granted PIVEG's motion to alter or amend the order on claim construction in light of the Federal Circuit's decision reversing the preliminary injunction imposed by this Court (Clerk's No. 163).² On August 27, 2004, the Court filed an order granting Plaintiff's motion to apply 35 U.S.C. § 295.³

¹ <u>See Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V.</u>, 301 F. Supp. 2d 970 (S.D. Iowa 2004) [hereinafter "<u>Kemin I</u>"].

² <u>See Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V.</u>, 319 F. Supp. 2d 939, 71 U.S.P.Q. 1637 (S.D. Iowa 2004) [hereinafter "<u>Kemin II</u>"].

³ Arguments on this motion were heard in conjunction with the hearing on Defendant's motion for summary judgment, as some of the issues between the motions overlapped. The Court's decision on the section 295 motion affects portions of the present motion for summary judgment, particularly, Defendant's assertion of noninfringement of the '564 patent. This will be discussed in greater detail supra, section D.3.

BACKGROUND FACTS⁴

The Federal Circuit reversed this Court's issuance of a preliminary injunction in an order filed March 17, 2004. In its decision, the Federal Circuit found that Kemin had not shown it is "likely to prove infringement, overcome any challenges to the validity and enforceability of the '714 patent at trial, and therefore have a reasonable likelihood of success on the merits of the case." In so finding, the court addressed potential inequitable conduct by Kemin and determined that a prior art reference cited by PIVEG may be material to the patentability of the '714 patent, that the materiality of the article is not negated by the fact that the method may have required some modification, and that the article was not cumulative of the prior art disclosed in the '714 patent.

ANALYSIS

Defendant and Counterclaim Plaintiff PIVEG has moved for summary judgment. PIVEG seeks a declaration that the '714 patent is unenforceable due to the inventors' inequitable conduct, that claim 1 of the '714 patent is invalid due to anticipatory prior art, and that PIVEG's purified lutein product does not infringe claim 1 of the '714 patent either literally or by the doctrine of equivalents. In addition, PIVEG seeks summary judgment that the '564 patent is unenforceable due to inequitable conduct, that claim 1 is invalid due to obviousness, and that PIVEG does not infringe claim 1 of the '564 patent

⁴ The Court is well aware of the background facts in this case and will not repeat the underlying facts here. Certain facts relevant to the pending motions will, however, be set forth in this section.

literally or by the doctrine of equivalents. Kemin resists PIVEG's motion, stating there are genuine issues of material fact on multiple issues, and further seeks to strike certain evidence relied upon in PIVEG's motion and amended memorandum in support of the motion.

A. Motion to Strike

Pursuant to Federal Rules of Civil Procedure 16(b), 16(f), 26(e)(2), 37(b)(2), and 37(c)(1), Kemin moved to strike certain evidence relied upon by PIVEG in its motion for summary judgment, filed May 14, 2004, and in PIVEG's amended memorandum of law in support of its motion for summary judgment, filed May 27, 2004. Kemin contends that PIVEG asserts for the first time in its briefing that a 1968 magazine article is anticipatory prior art and that it renders the '714 patent obvious. As this assertion was not made until well after the March 22, 2004, close of discovery, Kemin contends PIVEG effectively prevented Kemin from pursuing appropriate discovery on this issue. Consequently, Kemin asserts that PIVEG should be precluded from asserting the article in question, Kuzmicky *et al.*, *Pigmentation Potency of Xanthophyll*, 47 Poultry Science 389 (1968) [hereinafter "Kuzmicky article"], as anticipatory to the '714 patent.

1. Standard for Motion to Strike

The purpose of the modern discovery procedure is to narrow the issues, eliminate surprise, and achieve substantial justice. <u>Greyhound Lines, Inc. v. Miller</u>, 402 F.2d 134, 143 (8th Cir. 1968). The Supreme Court has explained the role of discovery:

The new rules, however, restrict the pleading to the task of general notice-giving and invest the deposition-discovery process with a vital role in the preparation for trial . . . The way is now clear, consistent with recognized privileges, for the parties to obtain the fullest possible knowledge of the issues and facts before trial.

<u>Hickman v. Taylor</u>, 329 U.S. 495, 501 (1947) (emphasis added). The Supreme Court further provided that "the deposition-discovery rules are to be accorded a broad and liberal treatment [because] [m]utual knowledge of all the relevant facts gathered by both parties is essential to proper litigation." <u>Id.</u>

The Federal Rules of Civil Procedure impose an affirmative duty on a party to seasonably amend a prior response "to an interrogatory" and a "request for production if the party learns that the response is in some material respect incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed. R. Civ. P. 26(e)(2). The Federal Rules penalize a party for failing to amend its discovery responses as required by not allowing the evidence to be used. Fed. R. Civ. P. 37(c)(1) ("A party that without substantial justification fails . . . to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any . . . information not so disclosed."). In addition, the Federal Rules allow the Court to impose additional sanctions, including: (1) attorneys' fees incurred as a result; (2) an order refusing to allow the disobedient party to support or oppose designated claims or defenses; and (3) an order prohibiting

that party from introducing designated matters in evidence and striking out the pleadings at issue or parts thereof. Fed. R. Civ. P. 37(c)(1); 37(b)(2)(B), (C).

In determining which sanction, if any, is appropriate, the Court "has wide latitude in imposing sanctions for failure to make discovery." Central States Industrial Supply, Inc. v. McCullough, 279 F. Supp. 2d 1005, 1025 (N.D. Iowa 2003) (quoting Coop. Finance Ass'n, Inc. v. Garst, 917 F. Supp. 1356, 1374 (N.D. Iowa 1996) (citations omitted)). Furthermore, when the circumstances evidence a willfulness and bad faith in the failure to permit discovery, determination of the proper sanction is entrusted to the discretion of the district court. Id. (citations omitted). Kemin contends that the Kuzmicky article is clearly responsive to its interrogatory requests, that it did not have fair notice of the Kuzmicky article, and that it had absolutely no notice that PIVEG would assert the article as invalidating prior art. Based on these principles, Kemin requests this Court issue an order striking the portions of PIVEG's motion for summary judgment and amended memorandum in support of that motion relating to the Kuzmicky article.

2. Argument

In its first set of interrogatories, served to PIVEG on October 4,2002, Kemin requested the following information:

INTERROGATORY NO. 8: Identify all patents, publications, other documents, things, witnesses, and all other sources of information you intend to rely upon to challenge the validity of the '714 and/or '564 patent.

INTERROGATORY NO. 12: If you contend the '714 patent and/or the '564 patent is invalid under 35 U.S.C. § 101, 102 and/or 112, state all facts and identify all documents that you believe support such a contention and identify the persons most knowledgeable about the information requested in this interrogatory.

INTERROGATORY NO. 13: If you contend the '714 and/or '564 patents are invalid under 35 U.S.C. § 103, state all facts and identify all documents that you believe support such a contention, including the level of ordinary skill in the art and each prior art reference relied upon with a detailed explanation of how each prior art reference is applied to each element of each patent claim that you contend is invalid, and identify the persons most knowledgeable about the information requested in this interrogatory.

It is clear that these interrogatories requested the disclosure of any prior art to be relied upon by PIVEG. PIVEG asserts the Kuzmicky article is invalidating prior art; however, PIVEG failed to mention the article in any of the responses to interrogatories PIVEG made prior to the March 22, 2004.

While PIVEG produced the article in February 2004 and the article was referenced in an earlier document produced by Kemin, Kemin contends it was not provided with fair notice of PIVEG's intention to assert the reference as invalidating prior art until well after the close of discovery. Kemin argues that the mere fact the article was produced in conjunction with this litigation is not sufficient to show Kemin was afforded fair notice, especially in light of the vast quantities of written documents produced in the present case. In other words, Kemin was not provided any notice that PIVEG would rely on the Kuzmicky article as invalidating prior art, an omission that may have impacted the discovery strategy chosen by Kemin and the substance of Kemin's expert reports. Kemin

further contends the book reference to the Kuzmicky article⁵ does not provide Kemin with fair notice of PIVEG's intent to use the article as anticipatory prior art.

Kemin served its interrogatories, specifically requesting the basis for any invalidity position, so that it would have fair notice in preparation of expert reports and during other phases of discovery. The Kuzmicky article is not merely supplemental production, but rather presents a new and separate basis for invalidating the '714 patent as anticipated and obvious in conjunction with other asserted prior art. By not disclosing the article sooner, Kemin asserts that PIVEG has deprived Kemin of the opportunity to have its experts opine on the relevance and impact of the asserted prior art, that this failure requires PIVEG to be sanctioned accordingly, and that PIVEG not be allowed to assert the Kuzmicky article as invalidating prior art.⁶

PIVEG resists Kemin's motion to strike arguing that Kemin has not been unfairly surprised and has suffered no prejudice. PIVEG claims that it did supplement its answers to Kemin's interrogatories within 30 days of the time it was in possession of the answers.

⁵ J. Christopher Bauernfeind, <u>Carotenoids As Colorants and Vitamin A Precursors</u> (1981).

⁶ Kemin also states this is not the first time PIVEG has attempted to circumvent the deadlines established in this case, and that given this pattern of conduct, PIVEG should be precluded from asserting the Kuzmicky article as invalidating prior art. PIVEG objects to these characterizations, contending it is Kemin that has issues regarding scheduling orders and deadlines. The Court finds no need to address these contentions and declines to enter into such bickering between parties. The Court will address Plaintiff's motion to strike solely on its own merits.

PIVEG contends that in order to answer the interrogatories, it needed to obtain the Kuzmicky article and analyze it to determine whether it supported the contention that the '714 patent was invalid. PIVEG asserts it did all of this in a timely manner.

PIVEG ordered the Kuzmicky article in January 2004 after noticing the citation in the Bauernfeind book excerpt. Upon reading the article, PIVEG deemed it relevant and produced it February 5, 2004. PIVEG then submitted a Freedom of Information Act request for the research records underlying the data reported in the article, the results of which contained nearly 200 pages of laboratory notes and were received by PIVEG on or about March 9, 2004. Upon review of this material, PIVEG's counsel determined it did support an invalidity argument as related to the '714 patent. This determination was made just before PIVEG began to draft its motion for summary judgment (mid-April), in which PIVEG included arguments relating to the Kuzmicky article. PIVEG then supplemented the relevant interrogatories two weeks after filing the motion for summary judgment. PIVEG contends this sequence of events belies Kemin's implications that PIVEG withheld the article with the intention of unfairly surprising Kemin.

PIVEG further contends Kemin has suffered no prejudice from inclusion of the article. Neither party has deposed any of the experts and as late as June 25, 2004, responsive expert reports were being filed. In fact, Kemin's expert has filed a report opining about the relative strengths and weaknesses of PIVEG's reliance on the Kuzmicky article. In addition, Kemin asked for, and received, an extension of time to

respond to PIVEG's motion for summary judgment. Accordingly, PIVEG asserts that the motion to strike should be denied as Kemin has been provided with fair notice of the article in question.

The Court finds PIVEG did not unduly delay in providing notice to Kemin regarding use of the Kuzmicky article. As soon as PIVEG became aware of the existence of the article, PIVEG began to analyze it for relevancy and potential use in the present litigation. PIVEG produced the article at this time. Upon determining its alleged applicability, PIVEG included the article in its motion for summary judgment and subsequently supplemented the relevant interrogatories. Kemin had sufficient time and opportunity to appropriately review and respond to the contentions raised by PIVEG in conjunction with the Kuzmicky article. Indeed, Kemin has provided expert testimony refuting PIVEG's contentions surrounding applicability of the article as part of Kemin's resistance to PIVEG's motion for summary judgment. Accordingly, the Court finds no reason to strike the Kuzmicky article and hereby denies Kemin's motion to strike the article.

B. Standard for Summary Judgment

The standard for summary judgment in a patent action is the same as in any other action. <u>Union Carbide Corp. v. American Can Co.</u>, 724 F.2d 1567, 1571 (Fed. Cir. 1984); see also <u>Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.</u>, 853 F.2d 1557, 1560-61 (Fed. Cir. 1988) (setting out standard for summary judgment in a patent case where the standard

mirrors that in any other type of case). Rule 56 of the Federal Rules of Civil Procedure provides that summary judgment should be rendered,

if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.

Fed. R. Civ. P. 56(c). To avoid summary judgment, the nonmoving party must make a sufficient showing on every essential element of its case for which it has the burden of proof at trial. See Celotex v. Catrett, 477 U.S. 317, 322-23 (1986).

The nonmoving party must go beyond the pleadings, and by affidavits, depositions, answers to interrogatories, and admissions on file, designate "specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e); Celotex, 477 U.S. at 324. While the quantum of proof that must be produced to avoid summary judgment is not precisely measurable, it must be enough evidence for a reasonable jury to return a verdict in its favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 257 (1986); see also Cortland Line Co. v. Orvis Co., 203 F.3d 1351, 1357 (Fed. Cir. 2000) ("A court may grant summary judgment when 'no reasonable jury could return a verdict for the nonmoving party."") (quoting Anderson, 477 U.S. at 248).

In considering a motion for summary judgment, the Court must view all the facts in the light most favorable to the nonmoving party and give that party the benefit of all reasonable inferences that can be drawn from the facts. <u>Matsushita Elec. Indus. Co. v.</u>

Zenith Radio Corp., 475 U.S. 574, 587-88 (1986) (citations omitted); Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1265 (Fed. Cir. 1991).

In addition, the Court "must view the evidence presented through the prism of the substantive evidentiary burden that would inhere at trial." Rockwell Int'l Corp. v. United States, 147 F.3d 1358, 1362 (Fed. Cir. 1998) (citations and quotations omitted). The question before this Court is whether the record, when viewed in a light most favorable to Kemin, shows there is no genuine issue as to any material fact and that PIVEG is entitled to judgment as a matter of law. See Intellectual Prop. Dev., Inc. v. UA-Columbia Cablevision of Westchester, Inc., 336 F.3d 1308, 1313 (Fed. Cir. 2003); Mansker v. TMG Life Ins. Co., 54 F.3d 1322, 1326 (8th Cir. 1995) (citing Celotex, 477 U.S. at 322-23, and Anderson, 477 U.S. at 249-50); SRI Int'l v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1116 (Fed. Cir. 1985).

The Court must approach a motion for summary judgment with great care, <u>SRI</u>

Int'l, 775 F.2d at 1116 ("Though speedy and inexpensive, summary judgment is nonetheless a 'lethal weapon' capable of 'overkill' . . . [and] experience has shown that a trial often establishes facts and inferences not gleanable from papers submitted pre-trial.")

(internal citations omitted), and only grant the motion if no genuine issues of material fact remain after viewing the facts and inferences in the light most favorable to the nonmoving party. RF Delaware, Inc. v. Pac. Keystone Techs., Inc., 326 F.3d 1255, 1266 (Fed. Cir. 2003); Toro Co. v. White Consol. Indus., Inc., 266 F.3d 1367, 1370 (Fed. Cir. 2001). The

Court will not "accept confusing or generalized testimony as evidence" in granting a summary judgment motion. Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1316 (Fed. Cir. 2002). In addition, the Court notes that summary judgment "is not designed to substitute lawyers' advocacy for evidence, or affidavits for examination before the fact-finder, where there is a genuine issue for trial." Continental Can, 948 F.2d at 1265.

C. Summary Judgment Issues on the '714 Patent

In its supplemental order on claim construction, this Court found "the limitations covered by claim 1 of the '714 patent are greater than about 90% pure, have significantly less than 10% of other carotenoids, and no traces of toxic chemicals." Kemin II, 319 F. Supp. 2d at 943. PIVEG contends that the '714 patent is unenforceable due to the inventors' inequitable conduct, that claim 1 of the '714 patent is invalid due to anticipatory prior art, and that PIVEG's purified lutein product does not infringe claim 1 of the '714 patent either literally or by the doctrine of equivalents.

1. Unenforceable Due to Inequitable Conduct⁷

Failure to disclose information material to patentability with intent to deceive the United States Patent and Trademark Office ("PTO") constitutes inequitable conduct, proof of which may render a patent unenforceable. <u>Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.</u>, 326 F.3d 1226, 1233 (Fed. Cir. 2003) (citing <u>Molins PLC v. Textron, Inc.</u>, 48

⁷ In the event the Court finds Kemin's conduct to be inequitable during the prosecution of the '714 patent, PIVEG reserves its right to request attorneys' fees based on 35 U.S.C. § 285.

F.3d 1172, 1178 (Fed. Cir. 1995)). "Inequitable conduct includes . . . failure to disclose material information . . . coupled with an intent to deceive." <u>CFMT, Inc. v. CFM</u>

<u>Technology, Inc.</u>, 349 F.3d 1333, 1340 (Fed. Cir. 2003) (quoting <u>Molins PLC</u>, 48 F.3d at 1178).

Individuals associated with the filing of a patent, including the inventor, prosecuting attorney or agent, and "[e]very other person who [is] substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application," have a duty of candor and good faith in dealing with the patent office. 37 C.F.R. § 1.56(a), (c). The duty of candor "includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

The breach of the duty of candor may constitute inequitable conduct, which would render the patent unenforceable. Smith Int'l, Inc. v. Hughes Tool Co., 759 F.2d 1572, 1578 (Fed. Cir. 1985). A finding of inequitable conduct requires (1) that the withheld reference be material, (2) that there was an intent to deceive in withholding the reference, and (3) a balancing of the degree of materiality and intent in light of the public interest.

N.V. Akzo v. E.I. Dupont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1987). Once the threshold of materiality and level of intent are found, the Court must conduct a balancing test between the levels of materiality and intent, with the ultimate determination of

inequitable conduct within the discretion of the Court. <u>Union Pac. Res. Co. v. Chesapeake</u> <u>Energy Corp.</u>, 236 F.3d 684, 693 (Fed. Cir. 2001).

Information is material when it is not cumulative to information already of record and it establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim. 37 C.F.R. § 1.56(b)(1). "There is no duty to submit information which is not material to the patentability of an existing claim." 37 C.F.R. § 1.56(a). Materiality is a question of fact, Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1366 (Fed. Cir. 2001), that must be established by clear and convincing evidence. Union Pac. Res. Co., 236 F.3d at 693. "Materiality is not limited to prior art, but instead embraces *any* information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent." GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001) (citing Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380, 1382 (Fed. Cir. 1998)). Similarly, materiality is not confined to matters reflected in the claims of a patent. Hoffman-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1367 (Fed. Cir. 2003).

Intent is also a question of fact that must be established by clear and convincing evidence. See Purdue Pharma L.P., 237 F.3d at 1366. It is improper to infer an intent to deceive from the mere fact that some material information was not disclosed. <u>Union Pac. Res. Co.</u>, 236 F.3d at 694. In other words, there must be a factual basis for finding deceptive intent on the part of an applicant or his representative, <u>id.</u>, (quoting <u>Hebert v. Lisle</u>

Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996)), even if the applicant may have known of the reference. See Braun, Inc. v. Dynamics Corp. of America, 975 F.2d 815, 822 (Fed. Cir. 1992); see also Hupp v. Siroflex of America, Inc., 122 F.3d 1456, 1465-66 (Fed. Cir. 1997) (finding that knowledge of a withheld reference does not necessarily establish that it was culpably withheld). Indeed, "[i]n a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference." Molins PLC, 48 F.3d at 1181; see also Northern Telecom, Inc. v. Datapoint, 908 F.2d 931, 939 (Fed. Cir. 1990) ("Given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required.").

However, because direct proof of wrongful intent is rare in inequitable conduct cases, "[t]he intent element of the offense is therefore in the main proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred." GFI, Inc., 265 F.3d at 1274. Thus, "intent may be inferred where a patent applicant knew, or should have known, that withheld information could be material to the PTO's consideration." Brasseller, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1375-76 (Fed. Cir. 2001). This means the individual must recognize the significance of the article and know of the duty to disclose. Rhone-Poulenc Rorer, 326 F.3d at 1239. In such situations, it will be difficult to establish subjective good faith sufficient to

overcome the inference of intent to mislead. <u>Id.</u>; <u>see</u>, <u>e.g.</u>, <u>id.</u> at 1240 (inferring intent to mislead based on failure to disclose a prior art patent with which the applicant was intimately familiar); <u>Critikon</u>, <u>Inc.</u> v. <u>Becton Dickinson Vascular Access Inc.</u>, 120 F.3d 1253, 1256 (Fed. Cir. 1997) (same).

The law requires patent applicants and their assignees to disclose potential conflicts to the examiner and "not to unilaterally make a determination that [the reference] was not prior art." GFI, Inc., 265 F.3d at 1274. "It is axiomatic that '[c]lose cases should be resolved by disclosure, not unilaterally by applicant." Critikon, Inc., 120 F.3d at 1257 (quoting LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 958 F.2d 1066, 1076 (Fed. Cir. 1992)). In addition, while establishing subjective good faith may prevent the inference of intent, "[a] mere denial of intent to mislead . . . will not suffice." Critikon, Inc., 120 F.3d at 1257 (citing FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987)). Moreover, ignorance of the law is no defense for withholding material prior art. See Brasseller, 267 F.3d at 1385 ("We reiterate that inventors represented by counsel are presumed to know the law.").8

In addition, there is an inverse relationship between the level of the materiality of the omitted information and the applicant's intent in inequitable conduct cases. <u>GFI</u>, <u>Inc.</u>, 265 F.3d at 1273 (quoting <u>Halliburton Co. v. Schlumberger Tech. Corp.</u>, 925 F.2d 1435, 1439 (Fed. Cir. 1991)). In other words, the more probative the information and the

⁸ Kemin was represented by counsel when it made the '714 patent application.

more intimately the individual is associated with the information, the lower the level of intent to deceive required. <u>Id.</u> However, "materiality does not presume intent," <u>id.</u> at 1274, as these elements are separate and essential components of inequitable conduct. <u>Manville Sales Corp. v. Paramount Sys., Inc.</u>, 917 F.2d 544, 552 (Fed. Cir. 1990) (citations omitted). The determination of whether the threshold level of intent is established is a separate inquiry than the inquiry into whether the threshold level of materiality is met. <u>See Upjohn Co. v. Mova Pharm. Corp.</u>, 225 F.3d 1306, 1312 (Fed. Cir. 2000) (citations omitted).

If the threshold levels of both materiality and an intent to deceive are established, the court must still weigh the degree of materiality and the degree to which intent has been established to determine, in light of all the circumstances, whether the applicant's conduct was so culpable that the patent should be held unenforceable. GFI, Inc., 265 F.3d at 1273. Evidence of good faith must also be considered in determining whether movant has shown inequitable conduct by clear and convincing evidence. Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1330 (Fed. Cir. 1998) (citing Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988)).

The burden of proving inequitable conduct is high, and the Federal Circuit has cautioned that summary judgment should be rarely granted on this issue. See Monsanto v. Bayer Bioscience N.V., 363 F.3d 1235, 1240 (Fed. Cir. 2004) (citing Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1190 (Fed. Cir. 1993)). Inequitable

conduct is not usually amenable to summary judgment because the element of "[i]ntent to mislead or deceive is a factual issue that, if contested, is not readily determined within the confines of Fed. R. Civ. P. 56." <u>KangaROOS U.S.A., Inc. v. Caldor, Inc.</u>, 778 F.2d 1571, 1576, 1577 (Fed. Cir. 1985) (quoting in addition, <u>Poller v. Columbia Broadcasting Sys., Inc.</u>, 368 U.S. 464, 473 (1962) ("[S]ummary procedures should be used sparingly . . . where motive and intent play leading roles . . .")).

a. The *Poultry Science* Article

Referring to the '714 patent, PIVEG contends that a prior art reference, namely, Tyzkowski, Juliusz, et al., Research Note: Preparation of Purified Lutein and its

Diesters from extracts of Marigold (Targetes erecta), 70 Poultry Science 651-54 (1991)

("the Poultry Science article"), exceeds the threshold of materiality. The Poultry Science article was published more than three years prior to the filing date of the '714 patent, thereby qualifying as a prior art reference. See 35 U.S.C. § 102(b). Kemin did not disclose the article to the PTO in the application or prosecution of the '714 patent. PIVEG contends the Poultry Science article is not cumulative of other references cited in the background section of the invention. Indeed, as the Federal Circuit observed, no other prior art that Kemin referenced discloses pure lutein from marigolds of 99.2% purity by High Performance Liquid Chromatography ("HPLC"). However, the Federal Circuit views were based on the record before it in relation to the preliminary injunction ruling

and admitted that the "record is not sufficiently developed for [the court] to decide [the issues of validity and enforceability of the '714 patent] conclusively in PIVEG's favor."

In its March 17, 2004 decision, the Federal Circuit determined the *Poultry Science* article "describes [a] composition that is likely within the scope of [claims 1, 2, and 4 of the '714 patent], and is therefore *prima facie* material to patentability, irrespective of whether it was clear that the method disclosed was fully operative." PIVEG contends that the *Poultry Science* article method was in fact fully operative as Jose Pichardo, PIVEG's Director of Research, was able to reproduce the results of the *Poultry Science* article without undue experimentation. Using this method, PIVEG produced purified lutein that was 99.5% by UV/visible spectrophotometry and 94.539% pure by HPLC. A former Kemin employee, Kay Lampe Hannasch, also testified in deposition that she used the Poultry Science article method, that it was operable, and that she obtained 99% pure lutein at least once from this method. Even if Pichardo or Hannasch modified the method described within the ordinary skill of the art, PIVEG points to the Federal Circuit's decision which stated that "the materiality of the article is not negated by the fact that the method disclosed therein may have required some modification in order to be operative." PIVEG argues that the *Poultry Science* article is *highly* material to the patentability of the '714 claims at issue because the article discloses a method resulting in purified lutein with less than 1% other carotenoids. PIVEG further asserts the methodology in the article would be expected to remove impurities such as toxic chemicals.

PIVEG next contends the record clearly indicates a sufficient level of intent to establish inequitable conduct. Dr. Chris Nelson, President of Kemin Industries, actively participated in the prosecution of the '714 patent and was well acquainted with the *Poultry Science* article and one of its co-authors, Dr. Pat Hamilton. Dr. Hamilton personally shared the method of the article with Kemin long before the application for the '714 patent was filed, and even before the article was published. The article itself acknowledges a longstanding relationship with Dr. Nelson and credits Kemin for its contributions to the article. Kemin's employees, under Dr. Nelson's direction, allegedly used and modified the methodology for years prior to filing the '714 application. Kay Lampe Hannasch testified she was provided with Hamilton's method by Dr. Nelson before the article was published and reported her progress in purifying lutein directly to Dr. Nelson.

Dr. Nelson stated that he did not submit the *Poultry Science* article reference to the PTO because his employees could not make the disclosed method work. PIVEG contends this statement contradicts the testimony of Kemin employees that used the method and found it to be operable. In fact, a modified version of the Hamilton method coupled with column chromatography was used at Kemin to produce purified lutein, samples of which were distributed to third parties in 1989.

PIVEG contends that because Dr. Nelson had intimate knowledge of the methodology disclosed in the *Poultry Science* article and that Kemin still failed to inform the PTO of the article, that this presents a clear case of inequitable conduct. PIVEG asserts that Dr. Nelson's statement "it never occurred to him" to disclose the article "amounts to no more than would a conclusory denial in a pleading which under [Rule 56] is insufficient to create a genuine issue." Paragon Podiatry Lab. Inc., 984 F.2d at 1191.

On the other hand, Kemin contends that there is no clear and convincing evidence that the nondisclosure of the *Poultry Science* article constitutes inequitable conduct with respect to the '714 patent. Kemin first contends there remain genuine issues of material fact on whether the *Poultry Science* article is material, specifically, whether the article discloses a purified lutein composition that is greater than 90% pure lutein and with no traces of toxic chemicals as the claim 1 of the '714 patent has been construed by this Court to require.

Dr. Khachik, a Kemin expert and the inventor of the '714 patent, does not believe the authors of the *Poultry Science* article confirmed their results because they use only a simple HPLC analysis to determine the composition. Dr. Larock shares this opinion, stating "it is well-accepted practice within the art to confirm the identity of a compound with at least one additional method of analysis, such as proton NMR or IR or UV/visible spectrophotometry or mass spectroscopy." In other words, according to Kemin the failure of the authors of the *Poultry Science* article to disclose a second, confirmatory means of analysis shows that the results are not reliable.

More importantly, Kemin avers that the *Poultry Science* article fails to disclose a composition of pure lutein that has no traces of toxic chemicals; rather, the method disclosed utilizes the toxic organic solvent toluene which would result in lutein crystals with traces of toluene. Dr. Khachik has stated he would never use the methodology disclosed in the *Poultry Science* article, in part because of its use of toluene, a high boiling point toxic solvent. Dr. Larock shares the opinion that the method disclosed in the *Poultry Science* article would result in a lutein containing traces of toluene. In addition, Kemin points to the opinion of the inventors of U.S. Patent No. 6,504,067, issued recently on January 7, 2003, and entitled "Process to Obtain Xanthophyll Concentrates of High Purity", who opined that the methodology disclosed in the *Poultry Science* article uses organic solvents and use of "such solvents can leave noxious residues which are trapped or occluded in the crystals." Kemin further disputes PIVEG's conclusory assertion that the *Poultry Science* methodology is expected to remove any impurities such as toxic chemicals.

Kemin asserts that, at best, the *Poultry Science* article is merely cumulative of the background information contained in the '714 patent because the article discloses lutein crystals that are still contaminated with toxic chemicals. See '714 Patent, col. 2, ll. 37-60. The novelty of the '714 patent is the isolation of purified lutein crystals that have *no*

⁹ Toluene's boiling point is 110°C. Exposing lutein samples to high heat could cause degradation and isomerization.

traces of toxic chemicals. Thus, Kemin contends the *Poultry Science* article is cumulative and cannot establish a *prima facie* case of unpatentability.

Kemin notes that the Federal Circuit decision only found it was *likely* the *Poultry Science* article was *prima facie* material to patentability. Kemin claims the Federal Circuit, in addition to only having a fledgling record before it, just took into consideration the percentage of lutein crystals in the composition disclosed but did not address whether the article discloses a methodology that results in lutein crystals that have no traces of toxic chemicals. For these reasons, Kemin contends PIVEG has not demonstrated by clear and convincing evidence that the *Poultry Science* article is relevant, or more specifically, that PIVEG provides no evidence the method disclosed in the article will result in lutein crystals with no traces of toxic chemicals.

Kemin argues further that PIVEG has failed to identify any evidence of an intent to deceive. The inventor of the '714 patent, Dr. Khachik, had no knowledge of the *Poultry Science* article during the prosecution of the '714 patent.¹⁰ Dr. Khachik has also testified that he does not believe the article's methodology would result in the reported 99% pure lutein and cited several reasons in support of this belief.

Kemin also argues that PIVEG has produced no evidence that Dr. Nelson, President of Kemin Industries, considered the article to be material or intentionally withheld

¹⁰ Dr. Khachik was not aware of the article until the prosecution of the corresponding international application, which occurred after the '714 patent had issues, and that upon reading the article, was "very confident that it had nothing to do with [his] invention."

the reference with an intent to deceive. While Dr. Nelson was aware of the article, he did not believe it was material because the disclosed methodology would result in lutein with traces of toxic solvents unsuitable for human consumption and because Kemin employees had been unable to get the method to work. On this basis, Dr. Nelson believed there was no need to submit the article, and has testified that decision was not based on an intent to deceive the PTO.

Kemin claims the evidence shows that the method disclosed in the *Poultry Science* article was simply not operative. Drs. Khachik and Larock believe the method disclosed in the *Poultry Science* article is inoperable. Dr. Nelson discusses via affidavit Kemin's attempts at reproducing the results and attaches a laboratory record showing Kemin was only able to obtain a waxy precipitate and not lutein crystals. Kemin notes that Kay Hannasch's laboratory notebook contains a written record of Kemin's attempt at replicating the *Poultry Science* article method, but that there is no recorded reference to a successful attempt. In addition, PIVEG's Mr. Pichardo had to modify the method in order to obtain lutein crystals. According to Kemin, these facts at the very least generate a genuine issue as to whether the *Poultry Science* method was fully operative, thereby precluding summary judgment.

Finally, Kemin contends that no balancing is warranted because PIVEG has failed to establish the requisite levels of both materiality and intent to deceive. If the Court were to go on to the balancing element, Kemin points out there is ample evidence of Dr.

Nelson's good faith, especially considering his sincere belief the *Poultry Science* method did not work. Kemin's failure to use the method disclosed in the article indicates the method was not operable and this disputed fact alone supports denial of PIVEG's motion for summary judgment.

PIVEG responds by asserting that Kemin cannot refute the materiality of the *Poultry Science* article, as a reasonable examiner would have considered the reference pertinent to the patentability of the invention. Moreover, Kemin's attempt to discount the article as unreliable is unsupportable and is only based on the opinions of the inventor and a hired expert. The *Poultry Science* article has been cited as prior art for the last thirteen years, and both Dr. Khachick and Kemin have cited it as prior art, Kemin in its '564 patent application. PIVEG asserts Kemin had the article prior to publication and successfully experimented with the method. In any event, Kemin was required to disclose the article to the PTO and then prove the article's method is suspect during the prosecution of the patent.

In addition, PIVEG asserts that an inference of intent is entirely proper in the present case based on the facts in the record along with additional circumstantial evidence of intent. For example, Dr. Nelson corresponded with one of the article's authors and directed his employees to experiment with the method. Kemin's only allowable choice was to disclose the article to the PTO, and Kemin's unilateral decision to withhold it is evidence of an intent to deceive. PIVEG further argues that Kay

Hannasch's inability to *consistently* reproduce the results is irrelevant, as she was able to reproduce the results on at least one occasion, despite the fact that she held only a bachelor's degree.¹¹

Based on the current record, the Court finds there still remain genuine issues of material fact as to whether the *Poultry Science* article is material and whether Kemin had the requisite intent to deceive in not disclosing the article to the PTO as part of the '714 patent application. Specifically, the Court finds questions of fact exist as to whether the methodology disclosed by the *Poultry Science* article would result in lutein with no traces of toxic chemicals given its use of the organic solvent toluene, whether the methodology disclosed by the *Poultry Science* article was enabled and how this affected Kemin's view of the article's method, and whether Kemin had any intent to deceive the PTO during the prosecution of the '714 patent. Accordingly, the Court cannot find inequitable conduct as a matter of law based on Kemin's alleged failure to disclose the *Poultry Science* article. Therefore, the Court will not find the '714 patent unenforceable on this basis at the present time.

One of ordinary skill in the art for the '714 patent would typically have possessed a level of skill consistent with a Ph.D. in Chemistry or Organic Chemistry with at least two (2) years of work or academic experience in Organic Chemistry. To be enabling, "the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation." Minnesota Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1306 (Fed. Cir. 2002).

b. Self-Generated Material

PIVEG also asserts the '714 patent is unenforceable due to Kemin's pattern of inequitable conduct in failing to disclose material information which was self-generated. Specifically, PIVEG claims that Kemin failed to disclose that in the late 1980's and early 1990's it was working to develop its own method for producing purified lutein as an analytical standard. Prior to 1990, Tony Sky, Kemin's former Director of Research in Organic Chemistry, reported producing lutein that was nearly 95% pure. Kemin distributed this lutein to third parties with restrictions on its use.

In addition, former employee Hannasch testified on her experimentation with lutein purification methods other than that disclosed by the *Poultry Science* article, achieving 92% lutein purity from one of these other methods. The procedure she used to achieve this result came from searching through the literature for simple methods of separating and crystallizing various components of marigold oleoresin.

Kemin did not disclose to the PTO either the production and limited public dissemination of purified lutein, or the results of Hannasch's testing and her literature search. PIVEG argues this information is material to the patentability of claims 1, 2, and 4 of the '714 patent, and the failure to disclose it to the PTO constitutes inequitable conduct.

Kemin claims that this information does not even meet the threshold for materiality. Kemin claims the efforts to develop a method for producing purified lutein as an analytical standard differ significantly from the '714 patent as these efforts utilized toxic organic

solvents. Kemin argues that even if material, PIVEG fails to present any evidence or argument that Kemin believed the information was material or that Kemin withheld the information with an intent to deceive.

Both Sky and Hannasch used methane, a toxic solvent that would have resulted in purified lutein with traces of toxic chemicals. In addition, Sky testified he was not aware of any other goals for his efforts. The specification of the '714 patent states methanol is not normally recommended; however, the patent itself claims the use of toxic solvents, such as methanol and methylene chloride. See '714 Patent, col. 10, claims 8, 10, 14. At the very least, this gives rise to fact questions on whether Kemin's research to obtain purified lutein for use as an analytical standard that was conducted prior to the '714 patent would have been material to the patentability of the '714 patent, given the use of the organic solvents that would result in lutein with traces of toxic chemicals.

The Court finds there still remain genuine issues of material fact as to whether the Kemin's research prior to the '714 patent application was material and whether Kemin had the requisite intent to deceive in not disclosing this information to the PTO as part of the '714 patent application. Accordingly, the Court cannot find inequitable conduct as a matter of law for Kemin's alleged failure to disclose the self-generated material, particularly on the meager evidence presented by PIVEG on this issue. Therefore, the Court will not find the '714 patent unenforceable on this basis at the present time.

2. Invalidity

a. Anticipation

"A patent shall be presumed valid." 35 U.S.C. § 282. To overcome the presumption of validity, the challenging party must prove facts supporting a determination of invalidity of the patent by clear and convincing evidence. Schumer, 308 F.3d at 1315 (citations omitted); see also Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1274-75 (Fed. Cir. 1995). Whether a patent is anticipated is a question of fact, Rockwell Int'l, Inc., 147 F.3d at 1363, and the burden of proving invalidity on summary judgment is high. Schumer, 308 F.3d at 1315.

Anticipation prevents patentees from claiming that which is covered by prior art.

See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1378 (Fed. Cir. 2001) (providing "that which would literally infringe if later anticipates if earlier"); Atlas Powder Co. v. Ireco, Inc., 190 F.3d 1342, 1346 (Fed. Cir. 1999) (stating that "if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated"). "Anticipation under [35 U.S.C.] § 102(a) requires that the identical invention that is claimed was previously known to others and thus is not new." Continental Can, 948 F.2d at 1267. A claim is invalid due to anticipation only when a prior art reference discloses each and every limitation of the claim. 35 U.S.C. § 102(a); see also Merck & Co. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1372 (Fed. Cir. 2003) (finding that an anticipating reference must

describe all of the elements and limitations of the claim in a single reference); <u>Schering Corp. v. Geneva Pharms., Inc.</u>, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (finding that "a prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates").

However, the anticipatory reference need not expressly disclose every feature of the claimed invention as long as the missing limitations are inherent in the single reference. Schering Corp., 339 F.3d at 1377 (citing Continental Can Co., 948 F.2d at 1268). For a reference to be anticipatory when it is silent about an asserted inherent characteristic, a court may go to extrinsic evidence to fill such gaps in the reference; however, "[s]uch evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art." Continental Can Co., 948 F.2d at 1268. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." In re Olerich, 666 F.2d 578, 581 (CCPA 1981) (quoting Hansgirg v. Kemmer, 102 F.2d 212, 214 (CCPA 1939)) (emphasis added).

Anticipation must, however, enable one of skill in the field of the invention to make and use the claimed invention. Merck & Co., 347 F.3d at 1372. Thus, a claimed invention is not anticipated by a prior art reference if the allegedly anticipatory disclosures are not enabled. Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research,

346 F.3d 1051, 1054 (Fed. Cir. 2003); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1354 (Fed. Cir. 2003). "Enablement requires that 'the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation." Elan Pharms., Inc., 346 F.3d at 1054 (quoting Chemque, Inc., 303 F.3d at 1301). In other words, "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art." Ben Venue Labs, 246 F.3d at 1379 ("[A]nticipation does not require the actual creation or reduction to practice of the prior art subject matter.") (citing In re Donahue, 766 F.2d 531, 533 (Fed. Cir. 1985)); see also Schering Corp., 339 F.3d at 1377.

Whether a disclosure is enabling under 35 U.S.C. § 112 is a question of law based on underlying factual inquiries. <u>Elan Pharms., Inc.</u>, 346 F.3d at 1054; <u>Enzo Biochem, Inc. v. Calgene, Inc.</u>, 188 F.3d 1362, 1369-70 (Fed. Cir. 1999). When evaluating a defense of invalidity for anticipation, an accused infringer is entitled to have the court presume the enablement. <u>Amgen Inc.</u>, 314 F.3d at 1355. The patentee may argue, however, that the relevant disclosures are not enabled and therefore not pertinent prior art, and the Court can determine that the disclosures are not enabled and exclude that particular prior art in the anticipation inquiry based on that evidence. <u>Id.</u> Therefore, the Court must determine whether the allegedly anticipatory prior art reference contains every element of the '714 patent claims, either expressly or inherently, and whether the

patent is enabled. Moreover, PIVEG must establish the evidence of invalidity by clear and convincing evidence, a high burden on a summary judgment motion. <u>Schumer</u>, 308 F.3d at 1315.

i. The Poultry Science Article

PIVEG contends that the *Poultry Science* article anticipates, and therefore invalidates, claims 1, 2, and 4 of the '714 patent. The first limitation of claim 1 is that the lutein "be greater than 90% pure." To achieve this limitation, most of the marigold plant material is removed from the composition during the process, such that the process produces a composition that is at least 90% lutein as measured by UV/visible spectrophotometry. PIVEG claims it was able to practice the *Poultry Science* method and produce lutein with greater than 99% purity as measured by UV/visible spectrophotometry without undue experimentation. The article discloses an HPLC measure of 99.2% purity. Thus, according to PIVEG, the *Poultry Science* article inherently discloses a composition that would be at least 90% lutein as measured by UV/visible spectrophotometry in conjunction with HPLC, thereby anticipating the first limitation of claim 1. PIVEG then points to the HPLC measure of 99.2% disclosed in the article as indicating significantly less than 10% of the composition consists of other carotenoids, thereby anticipating the second limitation of claim 1.

PIVEG subsequently asserts the *Poultry Science* article also meets the third limitation of claim 1 that there be "no traces of toxic chemicals." PIVEG avers that

removal of toxic solvents was well within the ordinary skill of the art at the time the article was published. PIVEG claims that Mr. Pichardo successfully reproduced the results of the article and removed toxic chemicals without any undue experimentation, and both he and Tony Sky testified such processes were available in 1994 and earlier. In addition, former Kemin employee Hannasch testified that if crystals are obtained, and PIVEG points out the article discloses lutein crystals, then there are no residual solvents within the crystals. Accordingly, PIVEG contends that all of the limitations of claims 1, 2, and 4 are anticipated by the *Poultry Science* article and are therefore invalid.

Meanwhile, Kemin contends that the *Poultry Science* article fails to disclose all of the limitations of the '714 patent and therefore cannot be considered anticipatory. Kemin asserts there is at least a genuine dispute regarding whether the article discloses lutein "greater than 90% pure," as required by the first limitation of claim 1. The article only discloses lutein purity of 99.2% as measured by HPLC whereas this Court's order on claim construction found lutein purity is to be measured by UV/visible spectrophotometry in conjunction with HPLC.¹² As previously noted, Dr. Khachik criticized the

¹² The construction of claim 1 *requires* lutein be measured by UV/visible spectrophotometry in conjunction with HPLC. As this Court stated:

The Court finds the evidence is undisputed a person of ordinary skill in the art at all material times would recognize UV/visible spectrophotometry in conjunction with HPLC is the correct method of measurement to determine lutein purity, and therefore must necessarily be considered the proper method of measurement for purposes of the '714 patent.

Kemin I, 301 F. Supp. 2d at 988.

results of the article in part due to the lack of a second method of analysis. Dr. Larock agreed with the premise of this criticism. In fact, nowhere in the article is UV/visible spectrophotometry referenced. PIVEG relies on the expert report of Ron Daignault, which simply restates the conclusions made in the article itself without further analysis or evidence, and the purported results of Mr. Pichardo, who used a modified version of the article's methodology.

Kemin further claims that the *Poultry Science* article fails to disclose the third limitation, that the lutein contain "no traces of toxic chemicals." As discussed earlier, the *Poultry Science* method employs the use of toluene which indicates the method cannot produce a purified lutein product with no traces of toxic chemicals. Toluene is not considered a safe product, is not acceptable for use in food processing, and has a toxic effect in humans. Despite PIVEG's assertions to the contrary, Kemin contends that the *Poultry Science* article fails to discuss the removal of any such toxic solvents from the resulting lutein. In fact, as the method disclosed in the article is directed towards the preparation of lutein for animal feed, there is no need to prepare lutein free of toxic solvents.

In addition, Kemin contends there is a genuine issue of material fact as to whether the *Poultry Science* article discloses lutein with "significantly less than 10% of other carotenoids." PIVEG has not provided any evidence to support its assertion that this limitation is disclosed by the article. Rather, PIVEG relies on the notation that the HPLC

measure in the article indicates less than 10% of other carotenoids. Kemin argues that this conclusory assertion is insufficient to meet PIVEG's burden for summary judgment. In addition, this Court has noted that the proper measure of purity consists of UV/visible spectrophotometry in conjunction with HPLC.

Finally, Kemin argues that the *Poultry Science* article is not enabling and therefore cannot serve as an anticipating reference. To overcome the presumption that the *Poultry Science* method is enabled, Kemin states that the record is replete with evidence indicating the disclosed methodology failed to work as described. Kemin itself unsuccessfully attempted to repeat the protocol of the article. Instead of getting lutein crystals, the method produced a waxy precipitate. Mr. Pichardo was only able to get lutein crystals by using a modified version of the method after he too first observed a paste in attempting to duplicate the *Poultry Science* methodology.

The Court finds that there is at least a genuine issue of material fact as to whether the *Poultry Science* article disclosed all of the limitations of the '714 patent. In addition, the Court is unable to determine as matter of law that the article's methodology was even enabled based on the record before it at this time. Therefore, the Court finds there are genuine issues of material fact as to whether the *Poultry Science* article anticipates the '714 patent. Accordingly, the Court cannot as a matter of law find the *Poultry Science* article anticipates the purified lutein product protected by the '714 patent, and the Court will not find the '714 patent invalid on this basis at the present time.

ii. The Kuzmicky Article¹³

PIVEG also argues that the Kuzmicky article also discloses a method for purified crystallized lutein and therefore anticipates claim 1 of the '714 patent and renders it invalid. Several compositions within the article are described as containing purified lutein at greater than 90% of total xanthophylls measured, with one sample containing lutein at 96.7% of the xanthophylls, leaving only 3.3% other carotenoids. The Kuzmicky article further states that "solvent was removed under vacuum" and discloses recrystallization of lutein "to give pure crystalline lutein." PIVEG contends that this article specifically discloses the methodology for obtaining a composition covered by claim 1, and anticipates every element of claim 1, thereby rendering the claim invalid.

Kemin contends the Kuzmicky article does not anticipate the '714 patent because it fails to disclose the limitations in claim 1 of the patent. Specifically, Kemin contends that the article does not disclose lutein greater than 90% pure as measured by UV/visible spectrophotometry in conjunction with HPLC. The Kuzmicky article describes the preparation of "pure lutein" using Ca(OH)₂-Celite chromatography, washed with a hexane-acetone mixture. The article fails, however, to provide any data confirming purified lutein was obtained. Moreover, it is highly likely that other carotenoids or xanthophylls would be present in the purified compound from this method as such

¹³ This article is the subject of Kemin's motion to strike. As the Court is denying that motion, this argument remains valid and will be analyzed by the Court.

compounds can be very difficult to separate by open chromatography. In addition, the Kuzmicky article purports to determine the purity of the extracted lutein using a simple spectrophotometric method, which is unlikely to have accurately determined the lutein purity within the extract, instead of UV/visible spectrophotometry in conjunction with HPLC as required by the '714 patent.

Kemin further asserts the Kuzmicky article fails to disclose the limitation that the lutein contain no traces of toxic chemicals. The method disclosed by the Kuzmicky article utilized the toxic organic solvent methanol, and therefore the resulting lutein would contain traces of the toxic chemical. While the article discloses a procedure for the extraction of alfalfa xanthophylls utilizing a series of hexane-acetone-methanol washes and then drying the extract under a vacuum to remove such solvents. Kemin contends that one skilled in the art would understand this would not be sufficient to remove residual amounts (i.e., "traces") of such solvents. Also, because lutein and methanol both contain an alcohol group, they would be difficult to separate, given the

¹⁴ This methodology cannot distinguish other carotenoids from xanthophylls from the lutein in the extract. In contrast, HPLC is the standard technique for separating and identifying carotenoids. However, HPLC was not available in 1968, when the Kuzmicky article was published. One expert even opined that there would have "been no reliable means to accurately determine the purity of the lutein in the mixture of xanthophylls that Kuzmicky obtains, given the limitations of the technology at the time of publication of the Kuzmicky article."

known chemical interactions between such alcohol groups, i.e., the possibility of hydrogen bonding between the alcohol groups of the methanol and lutein.

The Court finds there are genuine issues of material fact as to whether the Kuzmicky article anticipates the '714 patent because there are fact questions as to whether the article contains all of the limitations in the '714 patent. Specifically, there are issues regarding whether the Kuzmicky method teaches removal of all traces of toxic chemicals in addition to questions surrounding the method of purity measurement employed in the article. Accordingly, the Court cannot as a matter of law find the Kuzmicky article anticipates the purified lutein product protected by the '714 patent. Therefore, the Court will not find the '714 patent invalid on this basis at the present time.

b. Obviousness

A claim is also invalid if the invention "would have been obvious at the time the invention was made to a person having ordinary skill in the art to which [the invention] pertains." 35 U.S.C. § 103(a). As explained by the Federal Circuit,

Obviousness is ultimately a question of law that rests on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective considerations of nonobviousness.

Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1284-85 (Fed. Cir. 2000) (citing <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 17-18 (1966)). Additional factors to consider include "objective considerations such as commercial success, long felt need,

Prods., Inc., 21 F.3d 1068, 1071 (Fed. Cir. 1994) (citing Graham, 383 U.S. at 17). These objective criteria must always be considered and given whatever weight is warranted by the evidence presented. Knoll Pharm. Co. v. Teva Pharms. USA, Inc., 367 F.3d 1381, 1385 (Fed. Cir. 2004) (reversing summary judgment because district court failed to view evidence in light most favorable to patentee and failed to consider "failure of others" in finding a solution to the problem); see also Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1572 (Fed. Cir. 1996).

In making a determination of obviousness, the claims must be considered in their entirety and the invention is to be considered as a whole without the benefit of hindsight. Rockwell Int'l Corp., 147 F.3d at 1364. If a combination of references is used to establish obviousness, there must be some motivation to combine them, where the motivation may be evidenced by the nature of the problem solved or the knowledge of one with ordinary skill in the art. Beckson Marine, Inc. v. NFM, Inc., 292 F.3d 718, 727-28 (Fed. Cir. 2002). The movant has the burden of proving that combining the references would suggest to one skilled in the art how to achieve a missing limitation with a reasonable likelihood of success. See Rockwell Int'l Corp., 147 F.3d at 1365.

"Throughout the obviousness determination, a patent retains its statutory presumption of validity, see 35 U.S.C. § 282, and the movant retains the burden to show invalidity of the claims by clear and convincing evidence as to underlying facts." <u>Rockwell Int'l Corp.</u>, 147 F.3d at 1364; see also <u>Knoll Pharm. Co.</u>, 367 F.3d at 1384 (finding

that in motion for summary judgment, the movant must prove by clear and convincing evidence that each challenged claim cannot reasonably be held to be nonobvious).

The inventor of the '714 patent described an alleged need for purified lutein for cancer trials. PIVEG contends that the '714 inventor's alleged need for purified lutein for cancer trials combined with the *Poultry Science* article, along with the level of ordinary skill in the art at the time of the '714 application, is enough to render claims 1, 2, and 4 of the patent obvious.

The *Poultry Science* and Kuzmicky articles both teach methods for producing purified lutein crystals, where the composition of lutein crystals is "greater than 90% pure" lutein. The *Poultry Science* article discloses a composition containing less than 1% other carotenoids and a method using marigold extract which would result in removal of at least other plant material. The Kuzmicky article describes removal of toxic solvents under vacuum. PIVEG contends that the alleged historic need for purified lutein provides the motivation necessary to combine the two articles, and this combination renders claims 1, 2, and 4 of the '714 patent obvious, thereby rendering the claims invalid.

Kemin maintains that neither the *Poultry Science* article nor the Kuzmicky article alone, or in combination, disclose the limitations of claim 1 of the '714 patent. In particular, neither reference discloses the limitation of "no traces of toxic chemicals." Kemin asserts that PIVEG has failed to supply any reason for combining the references that would warrant summary judgment. PIVEG does not cite to evidence to support the

assertion that the need for purified lutein for cancer trials would motivate one skilled in the art to combine an article for purifying lutein for an analytical standard in the poultry industry with an article disclosing the varying degrees of pigmentation of chicken feet caused by different xanthophylls. Kemin again states that neither reference suggests the need to remove toxic chemicals, and that the Kuzmicky article's use of a vacuum would not sufficiently remove the toxic solvent used.

Kemin further asserts the secondary factors of nonobviousness weigh heavily in favor of the validity of the '714 patent. Specifically, the record indicates the high commercial success of Kemin's purified lutein product¹⁵ and PIVEG's efforts to duplicate it.¹⁶ Kemin's lutein is now used in CENTRUM® brand formulations, which is the leading multi-vitamin in the United States. Other vitamin suppliers have also sought lutein from Kemin, and Kemin currently has signed "logo agreements" with 79 companies that use Kemin's lutein.

Kemin also contends the record is awash in evidence of a long-felt need for a purified lutein crystal product. This evidence includes the fact that lutein has the potential to

¹⁵ There was no identifiable U.S. market when Kemin first started selling purified lutein, but, according to Rodney L. Ausich, President of Kemin Foods, L.C., by 2001, "Kemin has built that market to over \$28 million in revenue."

¹⁶ For example, in a February 2001 communication (prior to this lawsuit), Chuck Grambill, PIVEG's Director of Business Development, congratulated Mr. Espinoza on his pricing, stating, "You did a great job with the revised pricing. You put the difference to Kemin at 10% for all the Lutein products."

help maintain healthy eyes by helping to prevent macular degeneration. The specification of the '714 patent indicates the need for a carotenoid composition of substantially pure lutein and that the '714 patent is the fulfillment of that need. The specification further indicates that prior to the '714 patent, the processes to obtain purified lutein were time-consuming and not economically feasible. The record further suggests a failure by others to produce purified lutein. Even the inventor of the '714 patent indicates he did not succeed at first in his efforts to produce purified lutein. PIVEG counters by merely stating that no facts exist to support a long-felt need or commercial success.

The Court finds there are genuine issues of material fact as to whether the *Poultry Science* article and the Kuzmicky article render the '714 patent obvious. Specifically, there remain issues over whether the articles would be combined by one skilled in the art and whether the articles together would teach the product protected by the '714 patent. PIVEG has not met its burden of proving that combining the references would suggest to one skilled in the art how to perform any missing limitation with a reasonable likelihood of success, especially considering the high presumption of validity that the '714 patent obtains. In addition, there are at least fact questions on the nonobviousness factors that make a finding of obviousness by the Court not appropriate at this time. Accordingly, the Court cannot as a matter of law find the *Poultry Science* and Kuzmicky articles render the '714 patent obvious.

3. Infringement

"Victory in an infringement suit requires a finding that the patent claim 'covers the alleged infringer's product or process,' which in turn necessitates a determination of 'what the words in the claim mean.'" Markman v. Westview Instruments, Inc., 517 U.S. 370, 374 (1996) ("Markman II") (quoting H. Schwartz, Patent Law and Practice 80 (2d ed. 1995)). Thus, the determination of whether the patent has been infringed is a two-step process, Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) ("Markman I"), aff'd, 517 U.S. 370 (1996), in which the burden is on the plaintiff. See Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1323 (Fed. Cir. 2001).

The first step is the interpretation of the patent, i.e., construction of the meaning and scope of the patentee's claims. Markman I, 52 F.3d at 976. This is a legal determination that is solely within the province of the court. Id. at 979; see also Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1304 (Fed. Cir. 1999). The Court's claim construction effectively sets forth the scope of the asserted claims. See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998).

The second step consists of comparing the properly construed claims with the accused product, <u>Markman I</u>, 52 F.3d at 976; <u>see also Deering Precision Instruments</u>, <u>L.L.C. v. Vector Dist. Sys., Inc.</u>, 347 F.3d 1314, 1324 (Fed. Cir. 2003); <u>Minnesota</u>

The Court construed the claims in both the '714 and '564 patents in two prior orders. See Kemin I, 301 F. Supp. 2d 970, and Kemin II, 319 F. Supp. 2d 939.

Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1570 (Fed. Cir. 1992), "to determine whether all of the claim limitations are present either exactly or by a substantial equivalent." Young Dental Mfg. Co. v. Q3 Special Prods. Inc., 112 F.3d 1137, 1141 (Fed. Cir. 1997). It is well settled that an allegedly infringing device must contain every claimed element of the invention or the equivalent of every claimed element. Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326, 1333 (Fed. Cir. 2001) (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997)); see also RF Delaware, Inc., 326 F.3d at 1266; Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211 (Fed. Cir. 1998); Stiftung v. Renishaw PLC, 945 F.2d 1173, 1178 (Fed. Cir. 1991).

If the accused product or process clearly falls within at least one of the claims, infringement has occurred. Graver Tank & Mfg. Co. v. Lind Air Products, Co., 339 U.S. 605, 607 (1950). This is generally a question of fact to be ultimately resolved by the fact-finder. Markman I, 52 F.3d at 976; Johnson & Johnson Orthopaedics, Inc., 976 F.2d at 1570; see also RF Delaware, Inc., 326 F.3d at 1266 (finding "infringement, either literal or under the doctrine of equivalents, is a question of fact"); Toro Co., 266 F.3d at 1369-70 (noting that summary judgment of noninfringement is only proper if no genuine issues of material fact remain upon viewing the facts and inferences in the light most favorable to the nonmovant and finding that because of the intensely factual nature of the equivalency inquiry, summary judgment of noninfringement under the doctrine of equivalents is proper

only if the record "leaves no room for a reasonable jury to find equivalence"); <u>Pitney</u>

<u>Bowes, Inc.</u>, 182 F.3d at 1304 (finding summary judgment of noninfringement is appropriate only if, after viewing the material facts in the light most favorable to the nonmovant, "there is no genuine issue whether the accused device is encompassed by the claims").

a. Literal Infringement

PIVEG contends that its lutein products do not literally infringe claims 1, 2, or 4 of the '714 patent. In construing the claims of the '714 patent, the Court concluded that UV/ visible spectrophotometry used in conjunction with HPLC analysis renders a specific, quantitative measurement of lutein purity for purposes of the '714 patent. The parties agreed with this construction, with Dr. Nelson testifying to that effect in the hearing on claim construction. It was further noted that one skilled in the art would use both techniques to determine lutein purity. Dr. Daignault, PIVEG's expert at the claim construction hearing, also testified that the determination of lutein purity was done through UV/visible spectrophotometry in conjunction with HPLC. Now, the parties dispute what exactly this method of measurement entails.

UV/visible spectrophotometry determines the amount of carotenoids present in a given sample. HPLC measures lutein as a percentage of total carotenoids. UV/visible spectrophotometry on its own does not measure lutein purity because it determines the amount of carotenoids in a given sample that may contain other materials. Upon hearing

the parties' contentions, the Court held in its order on claim construction that lutein purity is determined using UV/visible spectrophotometry in conjunction with HPLC analysis.

According to PIVEG, the Court's construction means that in order to determine lutein purity one would multiply the UV/visible spectrophotometry measure by the HPLC measure. On the other hand, according to Kemin, the method requires that HPLC analysis be used to separate the individual carotenoids, which are then measured with a particular detector, typically a UV/visible spectrophotometer. Both parties assert their interpretation is consistent with the Court's findings on claim construction.

Kemin contends that PIVEG is mistaken in asserting this "disputed" method of measurement and on this basis alone the motion should be denied. Kemin contends that PIVEG's method measures lutein content, which is compared to the entire product, instead of lutein purity, which is compared to the carotenoids present and which is what the '714 patent requires. Kemin further asserts this methodology is inconsistent with the Court's claim construction order, prior arguments of PIVEG's expert Dr. Daignault, PIVEG's previous arguments before the Court, and PIVEG's own marketing materials.

Meanwhile, PIVEG contends that UV/visible spectrophotometry measures the concentration of carotenoids, and that under the Court's construction, UV/visible spectrophotometry alone is an adequate measurement of lutein purity because almost all of the carotenoids are lutein and this method measures total carotenoids. HPLC supplements the UV/visible spectrophotometry reading by allowing the specified concentration

of lutein to be calculated relative to all other materials in the sample. Pointing to examples from the '714 patent specification for support, PIVEG contends that "[p]urity is . . . a measure of the concentration of lutein relative to all other substances in the material. It is not, as Kemin now urges, a measure of lutein weight percent relative to total carotenoid weight percent." PIVEG urges the Court to employ the method discussed by Kemin's own President, Dr. Nelson, i.e., multiplying the UV/visible spectrophotometry measure with the HPLC calculation.¹⁸

Kemin tested PIVEG's product for lutein purity prior to filing the present suit. That testing included measurements by UV/visible spectrophotometry and HPLC. Based on these tests, PIVEG notes that the average UV/vis measurement of its product was 76.24%, and the average HPLC measurement was 92.63%. The product of these two measures (70.62% multiplied by 92.63%) establishes the lutein purity of PIVEG's product, as tested by Kemin's scientists, is 70.62%. This is well below the level of purity required by the '714 patent. In addition, the PIVEG Certificates of Analysis referenced by Kemin would result in a 76% lutein purity under the correct method of measurement (852.19 grams of total carotenoids per kilogram, or 85% multiplied by 90.204% lutein by HPLC). Accordingly, PIVEG contends its product does not literally infringe the first limitation of claim 1 of the '714 patent as none of the referenced PIVEG lutein products

¹⁸ Each party's argument regarding infringement of the '714 patent is based on that party's interpretation of the required method of measurement. It is obvious that resolution of this issue will materially affect the ultimate determination of infringement.

have a purity concentration "greater than 90% pure," and thus cannot literally infringe the '714 patent as an product must meet all of the limitations to infringe.

PIVEG also asserts that its product does not contain "significantly less than 10% other carotenoids" as required by the second limitation of claim 1. "Significantly" is defined as a noticeably large amount or a fairly large amount. PIVEG's products contain only slightly less than 10% of other carotenoids, and some lots of the product actually contain more than 10% of other carotenoids. Specifically, PIVEG's marketing materials disclose a composition containing 87% ± 2% lutein, or 13% ± 2% carotenoids. Kemin's own testing revealed 92.63% lutein by HPLC, or 7.37% other carotenoids. Finally, in additional testing performed by Kemin in November 2001 (prior to this lawsuit), every sample of PIVEG's product, be it the oil or powder product, contained less than 90% lutein as compared to all other carotenoids. PIVEG asserts these results show PIVEG's product did not contain "significantly less than 10% other carotenoids," and that in many instances, PIVEG's products contained more than 10% other carotenoids, and therefore its product cannot literally infringe the '714 patent.

Finally, PIVEG asserts that its product does not literally infringe the limitation that the lutein contain "no traces of toxic chemicals." Kemin's testing of PIVEG's lutein's purity found lutein purity of only 70.62%, meaning that nearly 30% of PIVEG's product consisted of impurities that are not lutein, making it highly unlikely that the PIVEG product contains no traces of toxic chemicals. Indeed, the samples drawn by Kemin at various stages of PIVEG's process showed the presence of ethanol, hexane,

and methylene chloride and other toxic chemicals, even in the last stage of the process. Even though the levels of the toxic solvents are below the levels allowed by the FDA, it is argued PIVEG's products contain at least trace amounts of certain toxic chemicals and thus do not literally infringe claim 1.

Kemin counters by contending that PIVEG's purified lutein products literally infringe the asserted claims of the '714 patent. First, Kemin contends that PIVEG's lutein products meet the first two limitations of being "greater than about 90% pure" with "significantly less than 10% other carotenoids." Certificates of Analysis provided by PIVEG demonstrate that PIVEG's products contain a lutein purity of 90.204% and a zeaxanthin purity of 7.468%. PIVEG's own marketing materials advertise a lutein purity of 91% and 6.14-6.5% zeaxanthin. Tests conducted by Kemin indicate an average purity of 92.63% lutein and 6.55% zeaxanthin.

Kemin also asserts PIVEG's products literally infringe the limitation that the purified lutein have "no traces of toxic chemicals." Kemin contends that the level of

¹⁹ Although the parties have never raised a claim construction issue and this Court has not defined this limitation with respect to what constitutes a toxic chemical, this Court, the Federal Circuit, and PIVEG have all referenced the Food and Drug Administration ("FDA") standards, and Kemin urges the Court to do so here. According to Kemin, whether a chemical is toxic depends necessarily upon its concentration in the particular product at issue. For example, folic acid has many known benefits, including the prevention of birth defects; however, the FDA prohibits concentrations exceeding 400 micrograms preserving in breakfast cereals. See 21 C.F.R. Ch. 1, § 172.345(d). Thus, according to Kemin, if a particular solvent falls under the FDA standard, then that solvent would not be a "toxic chemical." In addition, due to the complexities involved in making a toxicity determination, that is, evaluating the amount for a given substance to

hexane was 23 ppm in its final product, which is below the allowed FDA standards of 25 ppm. Thus, according to Kemin, this level of hexane would not be considered a toxic solvent for purposes of literal infringement, or this at least gives rise to a fact question on the issue.

The Court finds there are still many genuine issues of material fact on the claim of direct infringement, thereby making summary judgment inappropriate. The factfinder will need to determine the correct manner of measurement to determine purity, how to determine "no traces" and what a person knowledgeable in the art would regard as toxic chemicals, and whether PIVEG's lutein product meets all of the limitations in the '714 patent. Accordingly, the Court cannot find as a matter of law that PIVEG's product does not directly infringe the purified lutein product protected by the '714 patent.

b. Doctrine of Equivalents

PIVEG also contends that its lutein products do not infringe claims 1, 2, or 4 of the '714 patent under the doctrine of equivalents. A doctrine of equivalents analysis

produce a toxic result and the time of exposure for a given substance to produce a toxic result, Kemin argues that one of ordinary skill in the art would look to current FDA standards.

PIVEG disagrees with Kemin's assertions. According to PIVEG, "[t]hat the FDA would allow tiny amounts of a toxic substance in foods and dietary supplements does not vitiate a toxic substance's status as a toxic substance." In addition, PIVEG points out that the '714 patent makes no mention of FDA regulations, instead imposing its own bar on the level of toxic solvents. Thus, PIVEG contends that the "no traces of toxic solvents" limitation can require nothing other than "no traces." Again, resolution of this issue will materially affect the ultimate determination of infringement.

requires the Court to determine whether or not the allegedly infringing product performs substantially the same function, in substantially the same way, to obtain substantially the same result as the claimed invention. Dawn Equip.Co.v.Kentucky Farms Inc., 140 F.3d 1009, 1016 (Fed. Cir. 1998). A main indicator under this doctrine is whether the differences between the accused process and the claimed invention are "insubstantial." Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1349 (Fed. Cir. 1998).

In addition, the specification must provide enough information to enable one of ordinary skill in the art to make the claimed composition, i.e., the patent must provide an enabling disclosure. 35 U.S.C. § 112. "'To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.'" Plant Genetic Sys., N.V. v. DeKalb

Genetics Corp., 315 F.3d 1335, 1339 (Fed. Cir. 2003) (quoting Genentech Inc. v. Novo

Nordisk, A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (additional quotation omitted)).

Additionally, the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification. Genentech Inc., 108 F.3d at 1365.²⁰ However, "[t]he dispositive question of enablement does not turn on whether the accused product is enabled." Durel Corp. v. Osram Sylvania Inc., 256 F.3d 1298, 1306 (Fed. Cir. 2001).

PIVEG contends that the methodology of the '714 patent does not enable the production

²⁰ In addition, claims that are not supported by an enabling disclosure may be invalid. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987). This issue has not been asserted in the present motion.

of purified lutein like PIVEG's as it is less than 90% pure and does not have significantly less than 10% other carotenoids, and therefore PIVEG's lutein product cannot infringe under the doctrine of equivalents.

Indeed, the teachings of the '714 patent show the purity of resulting samples at or above 97%. No examples or description of compositions include purity levels less than 90%. Similarly, the '714 does not disclose any resulting composition having "significantly less than 10% other carotenoids." One example contained only 2.18% other carotenoids. The low level required for other carotenoids is necessary considering the inventors' described need for purified lutein to use in cancer trials. Also, the inventors chose to claim a composition of *significantly* less than 10% other carotenoids.

In addition, PIVEG asserts that its lutein, with a purity level near 70%, cannot be substantially equivalent to the limitation in the '714 patent that the lutein be "greater than 90% pure." This is especially true in light of the prior art disclosing a composition of 70% pure lutein, which the Examiner did not believe anticipated claim 1 of the '714 patent. In addition, PIVEG's product contains greater than or about 10% other carotenoids, which is closer to the starting material in Kemin's product than the final composition described.

Finally, the '714 patent teaches the desirability of a highly pure composition, and the Court construed this to require "no traces of toxic chemicals." According to PIVEG, this indicates claim 1 is strict in the requirement that the lutein product contain "no traces

of toxic chemicals." Because the PIVEG product contains chemical residues, albeit within the acceptable range under the FDA guidelines, it cannot infringe the '714 patent under the doctrine of equivalents.

Kemin states that PIVEG's purified lutein products infringe the asserted claims of the '714 patent under the doctrine of equivalents for the same reasons noted above in the literal infringement analysis. In addition, Kemin asserts that tests performed by Craft Technologies, Inc. ("Craft"), an independent third-party laboratory, indicate that PIVEG's purified lutein products have lutein purities ranging from 87.1% to 92.63%, zeaxanthin purities ranging from 6.55% to 9.6%, and cryptoxanthin purities ranging from 0.6% to 1.2%. Kemin proceeds to argue that PIVEG's purified lutein product has essentially the same purpose, quality, and function as the claimed carotenoid composition of the '714 patent, and thus meets the first and second limitations of claim 1.

Also, Kemin contends PIVEG's products infringe the limitation of "no traces of toxic chemicals" under the doctrine of equivalents. Specifically, PIVEG's marketing materials indicate its lutein products are suitable for use as dietary supplements in anti-oxidant formulas and as an antioxidant fortifier and colorant in foods and drinks, and thus have the same purpose as claimed carotenoid composition, i.e., acceptable for human

²¹ These tests were performed on PIVEG's oil, powder, and beadlet products, and samples taken during the second inspection of PIVEG's Celaya, Mexico, facilities. Results were reported September 17, 2003 (for the oil, powder, and beadlet products), and December 17, 2003 (for the sample taken at the November 14-15, 2003 inspection).

consumption. Further, Kemin argues that PIVEG's intended use of its lutein products is consistent with a product that does not contain traces of toxic chemicals, and with a similar composition and purity as FloraGLO® Lutein, thereby satisfying this limitation.

Finally, Kemin contends that the specification of the '714 patent enables the production of purified lutein like PIVEG's. Kemin contends that PIVEG notably fails to cite any authority for its argument to the contrary. Indeed, PIVEG cannot use its own product as the basis for an enablement analysis, as this issue is not determined by whether the accused product is enabled. Regardless, Kemin asserts that the '714 patent does enable one of ordinary skill in the art to produce lutein with a purity less than 90% and approximately 10% or less other carotenoids. Kemin points to examples in the patent specification that support this statement. See '714 Patent, col. 5, 1. 50 - col. 6, 1. 15; col. 6, 1l. 17-31. Further, PIVEG has not demonstrated that undue experimentation would be required to prove the '714 patent was not enabling to one skilled in the art.

The Court finds there are still many genuine issues of material fact on the claim of infringement under the doctrine of equivalents, thereby making summary judgment inappropriate on this contention. Again, in addition to the correct method of measurement to determine lutein purity, there still remain questions as to whether PIVEG's lutein product meets all of the limitations in the '714 patent under the doctrine of equivalents. Accordingly, the Court cannot find as a matter of law that PIVEG's product does not at least equivalently infringe the purified lutein product protected by the '714 patent.

D. Summary Judgment Issues for the '564 Patent

'564 patent:

The Court made the following determinations in construing the claim 1 of the

The saponification mixture is prepared by mixing the plant oleoresin with propylene glycol and an acqueous alkali solution of sodium or potassium hydroxide, collectively forming a fine dispersion (steps a and b). The saponification mixture contains 35-40% oleoresin, 30-45% propylene glycol, 5-10% alkali, and 7-15% water. The saponification mixture is maintained at a temperature ranging from about 60 to 80°C. This serves to saponify the xanthophyll diesters and form xanthophyll crystals (step c). Thereafter, approximately 3-19 volumes of water (per unit volume of the saponification mixture) are added at a temperature between about 60 and 80°C and mixed to form a diluted mixture containing xanthophyll crystals (steps d and e). Finally, the xanthophyll crystals are collected from the diluted mixture (step f). These are then washed and dried (step g). The "saponification reaction mixture" consists of four constituents at specified weight percentages in a ratio of about 4:4:1:1. The weight percentage of oleoresin and propylene glycol should together make up about 75 percent of the "saponification reaction mixture."

The Court also finds steps a and b need not be performed sequentially, as one of ordinary skill in the art would have understood these steps could be performed in a modified order and still achieve the same final result. The scope of the claim also covers processes that consist of all the listed steps along with other additional steps as long as the additional steps do not meaningfully change the process described in the claim. In addition, while the use of propylene glycol is necessary and cannot be substituted for, the claim does not exclude the use of any and all additional solvents as part of the process. The Court also construes the claim as allowing for the use of either sodium hydroxide or potassium hydroxide or some combination of both.

Kemin I, 301 F. Supp. 2d at 995-96. PIVEG contends that the '564 patent is unenforceable due to inequitable conduct, that claim 1 is invalid due to obviousness, and that PIVEG does not infringe claim 1 of the '564 patent literally or by the doctrine of equivalents.

1. Unenforceable Based on Inequitable Conduct of Non-Disclosure²²

PIVEG asserts that the '564 patent should be held unenforceable as a result of Kemin's inequitable conduct in obtaining the patent. Specifically, PIVEG alleges that Kemin failed to disclose highly material information related to the use of propylene glycol by Kemin and others prior to the '564 patent application. PIVEG argues this nondisclosure was done with an intent to deceive the PTO.

Propylene glycol is essential to the process of the '564 patent. Rod Ausich,

President of Kemin Foods and co-inventor of the '564 patent testified that he personally

came up with the idea of trying propylene glycol in the saponification reaction. Dr.

Ausich knew propylene glycol was already being used in the poultry pigment industry

and his idea to use propylene glycol emanated in part from seeing crystals in poultry

pigments. Dave Sanders, the other co-inventor of the '564 patent, testified that Kemin

used propylene glycol in the saponification reaction for its poultry pigment products as

²² The legal standard the Court follows in determining whether a patent is unenforceable based on inequitable conduct is delineated by the Court in section C.1, <u>infra</u>, and will not be set forth again here. The Court will proceed to analyze the parties' contentions on this issue as they relate to the '564 patent.

early as the first production of the OroGlo® poultry pigment. Dr. Nelson also testified that Kemin used a propylene glycol in the manufacturing process for poultry grade pigment to act as a solvent in the saponification reaction, and documentation from Kemin showed residual propylene glycol present in the poultry pigment products.

Despite their knowledge of the prior use of propylene glycol in production of poultry pigment and Kemin's own use of the solvent, Kemin did not disclose this information to the PTO in the application for or during the prosecution of the '564 patent. PIVEG contends that this information is unquestionably highly material to the methodology claimed in the '564 patent,²³ especially considering the Examiner made clear in his statement of allowance that patent protection was granted because use of propylene glycol during a saponification reaction was novel. PIVEG asserts that the high level of materiality, Dr. Ausich's testimony regarding the basis of his choice to use propylene glycol, and the admitted knowledge of Drs. Nelson and Sanders is enough to support a finding of inequitable conduct and render the '564 patent unenforceable.

Conversely, Kemin contends there is no clear and convincing evidence of inequitable conduct with respect to the '564 patent. Specifically, Kemin asserts that PIVEG has failed to establish that the prior use of propylene glycol in the poultry pigment

²³ PIVEG states in a footnote that "[t]he prior art use of propylene glycol for saponification is so highly material that it may in fact be anticipatory of claim 1 of the '564." PIVEG does not, however, ask the Court to make a finding on anticipation regarding this alleged prior art at this time.

industry is material. There at least exists a genuine issue as to whether the prior use of propylene glycol in the poultry pigment industry resulted in the formation of lutein crystals, and this has a direct bearing on the patentability of the '564 patent. The Examiner found the use of propylene glycol to produce crystals was novel. Kemin contends that the prior art does not teach this. Dr. Ausich stated he had occasionally seen crystals under the microscope when he conducted competitive analyses of products in the poultry pigment industry as part of his pervious employment. He did not know why propylene glycol was used in the poultry pigment industry nor was he aware whether it was used in the process to make OroGlo®, had no prior knowledge of the use of propylene glycol in saponification reactions to obtain lutein crystals, and only learned later of Kemin's use of propylene glycol in its process to produce its poultry pigment product.

Kemin further states that, prior to his research and experimentation, Dr. Ausich did not know that a chemical reaction using only marigold oleoresin, potash, and propylene glycol would result in the formation of lutein crystals of sufficient size and purity to be suitable for human consumption. At the time of the December 21, 1995 filing of the '564 patent application, there was no prior art disclosing a process utilizing propylene glycol to obtain lutein crystals.

While Kemin did use propylene glycol in the manufacturing of OroGlo® liquid for poultry pigmentations, it did not do so for the purpose of creating lutein crystals. Instead, propylene glycol was used to facilitate the movement of OroGlo® liquid between process

vessels prior to saponification.²⁴ Kemin was not aware at this time of propylene glycol's role in the formation of lutein crystals, and thus, this information was arguably not material to the '564 patent at the time of application.

Furthermore, Kemin maintains there is no evidence of an intent to deceive the PTO in conjunction with the prosecution of the '564 patent. PIVEG provides no support on this element beyond the base assertion that the materiality and knowledge of key individuals is enough to warrant a finding of inequitable conduct. Kemin asserts that PIVEG fails to show that any of the individuals associated with the '564 patent had knowledge of the alleged materiality of the prior use of propylene glycol in the poultry pigment industry or an intent to deceive the PTO. Additionally, it is argued that because the requisite levels of materiality and intent to deceive have not been established, there is no need to continue to a balancing of these elements.

PIVEG reiterates that the level of Kemin's prior knowledge and the '564 inventor's prior knowledge indicates the high level of materiality of the withheld information. In addition, PIVEG asserts the evidence of Kemin's intent is sufficiently high and not in issue. PIVEG argues that Dr. Ausich testified that he relied on his knowledge of prior art to design the process encapsulated in the '564 patent and that he knew propylene glycol was being used in saponification reactions in processes for producing poultry pigment. PIVEG contends that his post-deposition affidavit is nothing more than an attempt to

²⁴ Due to the highly viscous nature of unsaponified oleoresin, a lubricating solvent was necessary to transport the material from one vessel to another.

defeat summary judgment and that it provides contradictory answers than those obtained in the deposition, and this is further evidence of Kemin's intent to mislead the PTO.

The Court finds there still remain genuine issues of material fact as to whether Kemin's use of propylene glycol prior to the '564 patent application was material and whether Kemin had the requisite intent to deceive in not disclosing this information to the PTO as part of the '564 patent application. At the least, there are fact questions as to how Kemin used propylene glycol, the knowledge of Ausich on this use, and the use of propylene glycol by others during saponification to extract lutein crystals. In addition, PIVEG has not adequately addressed the level of intent needed to find inequitable conduct on the part of Kemin. Accordingly, the Court cannot find inequitable conduct as a matter of law for Kemin's alleged failure to disclose this information. Therefore, the Court will not find the '564 patent unenforceable on this basis at the present time.

2. Invalidity Due to Obviousness²⁵

PIVEG argues that claim 1 of the '564 patent is invalid due to the obviousness of the '714 patent in combination with prior art processes that used propylene glycol in saponification. Propylene glycol was being used in the production of poultry pigment before the '564 patent application, and PIVEG cites to numerous instances where Kemin or other individuals associated with the patent had knowledge of this or used it

²⁵ The Court provides the legal standard to determine a patent is invalid due to obviousness in section C.2.b, <u>infra</u>, and will not be set forth again here. The Court will proceed to analyze the parties' contentions on this issue as they relate to the '564 patent.

themselves.²⁶ PIVEG contends that the specification in the '714 patent provides the motivation to seek ways to produce crystalline lutein suitable for human consumption, and that the information concerning the use of propylene glycol would have been obvious to one skilled in the art. So that the remaining steps would have easily been within the grasp of one of ordinary skill in the art.

In addition, PIVEG notes that no substances other than propylene glycol were experimented with by the co-inventors of the '564 patent during the development process, as Dr. Ausich allegedly saw lutein crystals in the prior art in poultry pigment products using propylene glycol in the saponification reaction. Thus, according to PIVEG, claim 1 of the '564 patent is simply the result of combining prior art references, making the claim obvious and therefore invalid.

Kemin disagrees, and asserts that neither the '714 patent nor commercial use of propylene glycol in the poultry industry, alone or in combination, discloses the use of propylene glycol in a saponification reaction to promote the formation of lutein crystals for consumption by humans. Kemin contends that PIVEG has failed to meet its burden of showing by clear and convincing evidence how the combined teachings would suggest to one skilled in the art to develop the multi-step process covered by the '564 patent.

²⁶ <u>See</u> discussion <u>supra</u>, at section D.1 (discussing the use of propylene glycol as information not disclosed during the patent application as it affects validity and inequitable conduct by Kemin).

At the time of the '564 patent application, no prior art existed that disclosed a process utilizing propylene glycol to obtain lutein crystals, and contrary to PIVEG's characterizations, Dr. Ausich had no knowledge of the use of propylene glycol in the saponification reaction. At best, propylene glycol was being used by Kemin and others in the poultry pigment industry as an ingredient to facilitate movement of material between process vessels. Kemin later discovered, through research eventually leading to the '564 patent, that propylene glycol facilitates the formation of large lutein crystals,²⁷ a role it was unaware of prior to the experimentation leading to the '564 patent.

Kemin also asserts that the secondary factors of nonobviousness favor validity of the '564 patent. Specifically, the record establishes commercial success of Kemin's process to produce purified lutein crystal products. In addition, there was a long-felt need for such a process, especially considering lutein's potential use in nutritional supplements and food additives. The specification of the '564 patent recognized the limitations of the current processes for obtaining lutein suitable for human consumption. See '564 Patent, col. 1, ll. 52-61 ("Although chemical processes for the synthesis of xanthophylls from commercially available starting materials are known, such processes are extremely time-consuming, involve multiple steps, and have not provided an

²⁷ Specifically, Kemin determined that propylene glycol acts as a surfactant and crystallization enhancer during the saponification reaction, since it allows the lutein produced from the saponification reaction to become soluble. Thus, as more lutein is liberated during the saponification reaction, a super-saturated solution of lutein forms, which results in the formation of crystalline lutein.

economical process for production of xanthophylls."); col. 2, ll. 34-36, 40-42 (noting disadvantages of prior methods which were unsuitable for human consumption); col. 2, ll. 48-52 ("There is therefore a need for an economical means of production of an edible or comestible, substantially pure xanthophyll such as lutein or zeaxanthin in which the use of toxic or hazardous organic solvents is not employed.").

In addition, the specification notes the failure of others to produce a purified lutein fit for human consumption. Indeed, prior methods usually contained traces of toxic organic solvents making them unsuitable for human consumption. Finally, Kemin alleges that PIVEG attempted to copy Kemin's process by replicating the processes mentioned in the '564 patent to see what the product was and how it behaved based on statements made by a PIVEG executive. Kemin contends these considerations further support a finding of nonobviousness in relation to the '564 patent.

While PIVEG acknowledges that Kemin has asserted additional factors of nonobviousness, PIVEG avers that these assertions do not create issues of material facts.

They posit that Kemin was the exclusive licensee of the '714 patent and cannot now argue there was an urgent, long-felt need in the industry to come up with the process in the '564 patent. Also, the patent discloses an "increasing need," not a long-felt need.

Indeed, Kemin was already successful in this market. In addition, PIVEG states that Kemin's asserted failure to succeed by others is nothing more than a fabricated argument.

Moreover, PIVEG asserts that it did not attempt to copy Kemin's patent process; rather,

PIVEG employees designed around the patent, advancing the technology, and competed legally, exactly what the public policy underlying the granting of patents encourages.

The Court finds there are genuine issues of material fact as to whether the prior use of propylene glycol by Kemin and others renders the '564 patent obvious. Specifically, there remain issues over whether Ausich knew of the use of propylene glycol, whether propylene glycol was being used during saponification, and whether the use of propylene glycol was resulting in lutein crystallization. PIVEG has not met its burden of proving that combining the references would suggest to one skilled in the art how to perform any missing limitation with a reasonable likelihood of success, especially considering the high presumption of validity of the '564 patent. Accordingly, the Court cannot as a matter of law find this information renders the '564 patent obvious. In addition, there are at least fact questions on the nonobviousness factors making a finding of obviousness by the Court not proper at this stage of the proceedings.

3. Infringement

a. Literal Infringement or Infringement Under the Doctrine of Equivalents

PIVEG contends that its process does not literally infringe claim 1 of the '564 patent. Specifically, PIVEG argues that the PIVEG process does not use propylene glycol in its saponification reaction, does not use the same ratios of components, the same temperature ranges, or the same times. Because all of the elements of the claim are not met, PIVEG contends that a finding of noninfringement is warranted.

In the Court's August 27, 2004 Order on Plaintiff's Motion to Apply 35 U.S.C. § 295, the Court concluded that Kemin had shown a substantial likelihood of infringement of the '564 patent under the doctrine of equivalents. In that analysis, the Court discussed PIVEG's arguments that its process does not infringe that found in the '564 either literally or equivalently. The Court ultimately determined that Kemin had indeed shown a substantial likelihood of infringement, at least under the doctrine of equivalents. Further discussion of this issue is not necessary here. Suffice it to say, since there is a substantial likelihood of infringement of the '564 patent, there are, at the very least, fact issues precluding a finding of summary judgment of noninfringement.

b. PIVEG's New Process

Beginning in November 2003, PIVEG has been using a new process for producing purified lutein. This process does not use propylene glycol for any reason or at any point in the process. Otherwise, its new process is identical to the old one in the times and temperatures employed. Upon saponification, PIVEG adds an emulsifier other than propylene glycol to the reaction mixture and then completes the process exactly as before. As this Court unequivocally found the use of propylene glycol is required in claim 1 of the '564 patent,²⁸ based in part on the Examiner's statement of reasons for

²⁸ "The claim does not cover a process that substitutes another solvent in its place . . . Other solvents may be used in addition to, but not in place of, propylene glycol in the process covered by claim 1." <u>Kemin I</u>, 301 F. Supp. 2d at 993.

allowance,²⁹ PIVEG maintains that its modified process does not infringe claim 1 of the '564 patent either literally or equivalently.

As the '564 patent clearly requires the use of propylene glycol, PIVEG contends its modified process does not literally infringe the patent as it in no way uses propylene glycol. Likewise, PIVEG contends there is no equivalent that may be substituted for propylene glycol and still be covered by claim 1 of the '564 patent, and that therefore, PIVEG's current process cannot infringe under the doctrine of equivalents. Moreover, none of the three emulsifiers PIVEG employs in place of propylene glycol³⁰ is a 3-carbon organic dihydroxy alcohol like propylene glycol.³¹ Consequently, PIVEG's modified

²⁹ The Court cited to the Examiner's statement in its order on claim construction. <u>See Kemin I</u>, 301 F. Supp. 2d at 993. In the statement for allowance, the Examiner provided the following reasons:

The claims are drawn to producing xanthophyll crystals which comprises the steps of admixing a plant oleoresin with propylene glycol followed by alkali treatment . . . The claims of the present application are specifically drawn to propylene glycol treatment. It is apparent that the prior art does not recite propylene glycol specifically nor a motivation for propylene glycol treatment. Therefore, in the absence of a prior art teaching that would motivate one of ordinary skill in the art to use propylene glycol in producing xanthophyll crystals, the examiner has determined the application allowable.

³⁰ The process uses one of the following three emulsifiers in place of propylene glycol: glycerin, polysorbate 80, or polysorbate 60.

³¹ Glycerin is a 3 carbon alcohol having 3 hydroxy groups. Polysorbate 80 is a polyethylene sorbitan monooleate, which is a very large molecule containing over 100 carbons and 3 hydroxy groups. Polysorbate 60 is very similar in its properties to polysorbate 80. The polysorbates function as emulsifiers by holding water and oil in suspensions.

process is not equivalent to the '564 process for the additional reason that it does not an equivalent solvent as a substitute for propylene glycol.

Kemin asserts that a summary judgment determination with respect to PIVEG's "new" process is not appropriate at the present time, given that no discovery of this process has occurred. The modified process currently employed by PIVEG was put into place almost immediately following Kemin's second inspection of PIVEG's facilities and process. No documents exist concerning the new process, and the only information Kemin has received concerning the new process consists of a letter from PIVEG's counsel informing Kemin of the new process and limited questions in the deposition of Messrs. Espinoza and Pichardo. Kemin contends it is inappropriate to seek summary judgment on this new process based solely on the uncorroborated deposition testimony of two PIVEG employees. At best, Kemin argues, this new process should be the subject of a separate lawsuit, which Kemin reserves the right to bring at a later date; and any other result would prejudice Kemin.

PIVEG contends this posture by Kemin is disingenuous and that Kemin itself is to blame for its lack of discovery on this issue because it procrastinated in failing to pursue additional discovery prior to the close of discovery. PIVEG provided notice of the new process more than two months prior to the close of discovery. Kemin did not propound additional discovery requests, although it did question two PIVEG executives about the new process. To PIVEG's knowledge, Kemin has not even bothered to test or request samples of PIVEG's product made with the new process. According to PIVEG, these

failures are Kemin's alone, and Kemin should not now be allowed to argue it had insufficient discovery on this issue. In addition, PIVEG asserts that there is no prejudice to Kemin created by PIVEG's motion for summary judgment on the issue. If the Court finds the new process noninfringing, Kemin is not estopped from bringing a later suit if it finds evidence that PIVEG is not actually practicing that process.

The Court finds that there is not sufficient information on PIVEG's new process to warrant a finding of noninfringement as a matter of law at the present time. If PIVEG's new process is a proper subject for the current action at all, there remain sufficient issues of fact as to whether PIVEG's new process infringes the '564 process either literally or under the doctrine of equivalents. If PIVEG can establish that propylene glycol is not used at all in the new process, and that it is indeed utilizing the new process in the Celaya, Mexico, plant, then a finding of noninfringement may be established; however, PIVEG has not made a sufficient showing on the record before the Court at the present time for the Court to find as a matter of law that the new process does not infringe the '564 patent.

CONCLUSION

As previously noted, the Court **denies** Plaintiff's Motion to Strike (Clerk's No. 176). PIVEG acted promptly in providing notice of the material in question to the opposing party, and Kemin has not been unduly prejudiced by the use of the material. Therefore, the Kuzmicky article was considered in conjunction with the currently

pending motion for summary judgment and will be available for use during the upcoming trial.

The current motion for summary judgment embodies the difficulty encountered in many patent cases, i.e., it becomes a highly technical clash of experts. The burden on summary judgment is on the movant, in this case PIVEG, and this burden is especially high on the issues of invalidity, inequitable conduct, and obviousness as asserted here by PIVEG. The Court finds there still remain many genuine issues of material fact that preclude summary judgment on all of PIVEG's assertions. For the foregoing reasons, Defendant's Motion for Summary Judgment (Clerk's No. 164) must be **denied**.

IT IS SO ORDERED.

Dated this 2nd day of September, 2004.

JAMES E. GRITZNER, JUDGE/ UNITED STATES DISTRICT COURT